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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,408	03/03/2000	Kristin M. Lundy	PC10487A	7372

23913 7590 12/19/2002

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EXAMINER

JONES, DWAYNE C

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/518,408

Applicant(s)

LUNDY, KRISTIN M.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-9 and 11-21 are pending.
2. Claim 10 is cancelled as per the amendment of October 8, 2002.
3. Claims 1-9 and 11-21 are rejected.

### ***Response to Arguments***

4. Applicant's arguments with respect to claims 13 have been considered but Applicant's arguments filed October 8, 2002 have been fully considered but they are not persuasive with respect to claims 13-21 for the prior art reference of O'Malley et al. under 35 U.S.C. 103(a) as well as claims 1-21 over the judicially created doctrine of obviousness-type double patenting of Villalobos et al.

5. Applicants allege that O'Malley et al. teach of 3-amino-1,2-benzisoxazoles and not 3-(piperidinylalkyl)-1,2-benzisoxazoles. Also, applicants argue that there is no motivation to modify the 3-(aminoalkylamino)-1,2-benzisoxazoles with additional substituents, as taught by O'Malley et al. In addition, applicant argues that there is no suggestion or motivation to treat the disorders in companion animals in the instant application, whereas O'Malley et al. is directed to the treatment of various memory dysfunctions characterized by a decreased cholinergic function. Applicant also alleges that claims 1-21 are patentably distinct from claims 1 and 2 of Villalobos et al. of U.S. Patent No. 5,538,984 and consequently the rejection of obviousness double patenting should be withdrawn.

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6. In response to applicant's allegation that there is no motivation to modify the 3-(aminoalkylamino)-1,2-benzisoxazoles with additional substituents, it is noted that O'Malley et al. specifically teach that the variable of  $R^1$  is represented by hydrogen or an alkyl moiety, and that the variable of  $R^2$  is represented by *preferred* embodiment of the following group of  $-(CH_2)_m-C_5H_9N-R_6$ , (see from column 4, line 50 to column 5, line 34). From this teaching, one having ordinary skill in the art is provided with motivation to select these 3-(piperidinylalkyl) derivatives of 1,2-benzisoxazole especially when the prior art reference of O'Malley et al list these same compounds in their preferred embodiments.

7. In response to applicant's argument that there is no suggestion or motivation to treat the disorders in companion animals in the instant application, whereas O'Malley et al. is directed to the treatment of various memory dysfunctions characterized by a decreased cholinergic function, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). For these reasons, composition claims 13-21 are rendered obvious over the prior art reference of O'Malley et al. In addition, O'Malley et al. do in fact teach of pharmaceutical preparations of these derivatives of 1,2-benzisoxazoles, (see column 25).

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8. Next, applicant alleges that claims 1-21 are patentably distinct from claims 1 and 2 of Villalobos et al. of U.S. Patent No. 5,538,984 and consequently the rejection of obviousness double patenting should be withdrawn. In addition, applicant argues that Villalobos et al. is directed to "enhancing memory or treating Alzheimer's Disease" while the instant claims are directed to treating age-related behavioral disorders, cognitive dysfunction syndrome, involutive depression, memory loss, disorientation or confusion and inappropriate elimination, in companion animals. This allegation is unpersuasive because Villalobos et al. is directed to compounds and pharmaceuticals that, "are useful in enhancing memory in patients suffering from dementia and Alzheimer's disease", (see column 1, lines 13-18). First, the prior art reference of Villalobos et al. is specifically relevant to treating "mammals" which most certainly provides motivation to embrace companion mammals such as dogs and cats. In addition, it is well established in the art that both dementia as well as Alzheimer's disease are commonly associated with disorders afflicting older mammals. Accordingly, it would have been obvious to one having ordinary skill in the art to use the teachings of Villalobos et al. for treating age-related disorders, such as dementia, in a mammal, which would obviously include companion mammals.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 3-8, 11, 12 and 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 17-21 recite the limitation "Formula I" in line 1. There is insufficient antecedent basis for this limitation in the claim. Each of these claims fails to provide a structure to coincide with the compound of Formula I. It is suggested that the compound and the embodiments of Formula I be incorporated into an independent claim to obviate this confusion. Alternatively, these claims could be made to depend on claim 1, which does in fact incorporate the embodiments of Formula I.

12. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, instant claim 11 is currently dependent on cancelled claim 10, which renders the claim vague and indefinite.

***Claim Rejections - 35 USC § 103***

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. The rejection of claims 13-21 under 35 U.S.C. 103(a) as being unpatentable over O'Malley et al. of U.S. Patent No. 5,494,908 is maintained and repeated for both the above-stated and reasons of record. O'Malley et al. teach of the benzisoxazole compounds and that these compounds are anticholinesterase inhibitors. O'Malley et al. also teach that these compounds are effective in the treatment of Alzheimer's

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disease, (see abstract and columns 19-26). O'Malley et al. also teach of pharmaceutical preparations of these compounds, (see column 25). Although the prior art reference of O'Malley et al. do not specifically teach of treating of the cognitive disorders recited by the instant claims, O'Malley et al. do state the benzisoxazole compounds and their salts are effective in the treatment of various memory dysfunctions characterized by a decreased cholinergic function such as Alzheimer's disease, (see column 2, lines 19-25). Clearly, it would have been obvious to one having ordinary skill in the art to employ these benzisoxazole compounds for disorders related to memory dysfunctions where there is a decrease in the cholinergic function, as taught by O'Malley et al.

### ***Obviousness-type Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. The rejection of claims 1-9 and 11-21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S.

Patent No. 5,538,984 is maintained and repeated for the outstanding reasons as well as

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those cited above in paragraphs 4 and 8. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and U.S. Patent No. 5,538,984 are directed to the improving of a cognitive disorder for the improvement in memory or even treating dementia and Alzheimer's disease with the administration of the compounds of formula (I).

### ***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

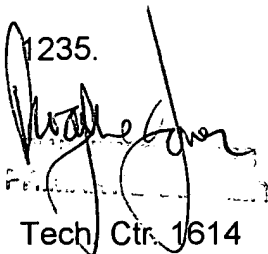
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-

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4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.  


Tech Ctr. 1614  
December 18, 2002